ATTN: MAIL STOP NON-FEE AMENDMENT
PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

Haynes, Joel R.
Wonderling, Ramani S.
Stinchcomb, Dan T.

Serial No.: 09/830,221

Filed: August 10, 2001

Atty. File No.: DE-3-C2-PUS

For: "CATIONIC LIPID-MEDIATED ENHANCEMENT OF NUCLEIC ACID IMMUNIZATION OF CATS"

Group Art Unit: 1648

Examiner: Foley, Shannon A.

RESPONSE

CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO COMMISSIONER FOR PATENTS, WASHINGTON, DC 20231, ON THIS 8TH DAY OF JULY 2003.

HESKA CORPORATION

By: Susan A. Gordon
Susan A. Gordon

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

This is in response to the Office communication mailed from the U.S. Patent and Trademark Office ("USPTO") on July 1, 2003. Applicants note that a complete Amendment and Response to the January 2, 2003 Office Action, was mailed to the USPTO on April 16, 2003. Enclosed herewith is a copy of Applicants' original Amendment and Response, Request for Extension of Time and Verified Statement (Declaration) Claiming Small Entity Status - Small Business Concern, filed April 15, 2003, along with the postcard acknowledgment showing these documents were received at the USPTO OIPE on April 21, 2003. Applicants do not believe any fees are due with today's response, but in the event fees are due, please debit Deposit Account 081930.

Respectfully submitted,

Dated: July 8, 2003

By: Richard J. Stern

Richard J. Stern, Ph.D.
Registration No. 50,668
Heska Corporation
1613 Prospect Parkway
Fort Collins, Colorado 80525
Telephone: (970) 493-7272
Facsimile: (970) 491-9976

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Examiner: Foley, Shannon A.

REQUEST FOR EXTENSION OF TIME

CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO COMMISSIONER FOR PATENTS, WASHINGTON, DC 20231, ON THIS 15TH DAY OF APRIL 2003.

HESKA CORPORATION

By: Susan A. Gordon
Susan A. Gordon

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Applicants respectfully petition for an extension of time under 37 CFR § 1.136(a) of one (1) month to respond to the Office Action mailed on January 2, 2003, with respect to the above-identified application, thereby extending the period for response from April 2, 2003 to May 2, 2003.

Applicants authorize the one-month extension fee of $55 to be charged to Deposit Account 081930. Applicants also enclose a Verified Statement (Declaration) Claiming Small Entity Status for a Small Business Concern. Please credit any overpayment or debit any underpayment to Deposit Account No. 081930.

Respectfully submitted,

Dated: April 15, 2003

By: Richard J. Stern

Richard J. Stern, Ph.D.
Registration No. 50,668
Heska Corporation
1613 Prospect Parkway
Fort Collins, Colorado 80525
Telephone: (970) 493-7272
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PATENT APPLICATION

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Group Art Unit: 1648

Examiner: Foley, Shannon A.

AMENDMENT AND RESPONSE
Under (37 CFR§1.111)

CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO COMMISSIONER FOR PATENTS, WASHINGTON, DC 20231, ON THIS 15TH DAY OF APRIL 2003.

HESKA CORPORATION

By: Susan A. Gordon
Susan A. Gordon

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In response to the Office Action mailed from the USPTO on January 2, 2003, Applicants request reconsideration based on the following amendments and remarks. Applicants also submit, herewith, a Request for a one-month Extension of Time extending the period for response from April 2, 2003 to May 2, 2003.

Amendments to the Claims

Please amend Claims as follows:

1. (Currently amended) A method to elicit an immune response to an antigen in a felid, said method comprising parenterally administering to said felid a composition comprising a purified nucleic acid molecule complexed with a cationic lipid, wherein said purified nucleic acid molecule encodes said antigen.

2 . (Currently amended) A method to deliver a purified nucleic acid molecule to a felid, said method comprising parenterally administering a composition comprising said purified nucleic acid molecule complexed with a cationic lipid.

3. (Currently amended) A method to protect a felid from rabies infection, said method comprising parenterally administering to said felid a composition comprising a purified nucleic acid molecule encoding rabies glycoprotein G, wherein said purified nucleic acid molecule is complexed with a cationic lipid.

4. (Currently amended) The method of Claim 2, wherein said purified nucleic acid molecule encodes a compound selected from the group consisting of an RNA molecule and a protein.

5. (Currently amended) The method of Claim 2, wherein said purified nucleic acid molecule encodes a protein that elicits an immune response in said felid.

6. (Original) The method of Claim 5, wherein said protein is selected from the group consisting of an antigen and an immunomodulator.

7. (Original) The method of Claim 1 or 5, wherein said immune response comprises an antibody response.

8.(Original) The method of Claim 1 or 5, wherein said immune response comprises a cell-mediated response.

9.(Original) The method of Claim 1 or 5, wherein said immune response protects said felid from disease.

10.(Original) The method of Claim 1 or 6, wherein said antigen is selected from the group consisting of a protozoan parasite antigen, a helminth parasite antigen, an ectoparasite antigen, a fungal antigen, a bacterial antigen, and a viral antigen.

11.(Original) The method of Claim 1 or 6, wherein said antigen is selected from the group consisting of a calicivirus antigen, a coronavirus antigen, a herpesvirus antigen, an immunodeficiency virus antigen, an infectious peritonitis virus antigen, a leukemia virus antigen, a parvovirus antigen, a rabies virus antigen, a *Bartonella* antigen, a *Yersinia* antigen, a *Dirofilaria* antigen, a *Toxoplasma* antigen, a flea antigen, a flea allergen, a midge antigen, a midge allergen, a mite antigen, a mite allergen, and a tumor antigen.

12. (Original) The method of Claim 1 or 6, wherein said antigen comprises rabies glycoprotein G antigen.

13. (Original) The method of Claim 1, 2, or 3, wherein said cationic lipid comprises a tetramethyltetraalkyl spermine analog lipid.

14. (Original) The method of Claim 1 or 3, wherein said composition further encodes an immunomodulator.

15. (Original) The method of Claim 1, 2, or 3, wherein said felid is selected from the group consisting of domestic cats, wild cats, and zoo cats.

16. (Currently amended) The method of Claim 1, 2, or 3, wherein the felid is selected from the group consisting of domestic cats, lions, tigers, leopards, panthers, cougars, bobcats, lynx, ~~bobcats, lynx,~~ jaguars, cheetahs, and servals.

17. (Original) The method of Claim 1, 2, or 3, wherein the felid is a domestic cat.

18. (Original) The method of Claim 1,3, or 5, wherein a single administration of said composition elicits an immune response.

19. (Original) The method of Claim 1, 3, or 6, wherein said step of administering enhances an immune response compared to administration of a naked DNA vaccine encoding said antigen of Claim 1 or 6 or said rabies glycoprotein G of Claim 3 to a felid.

20. (Original) The method of Claim 1, 2, or 3, wherein said step of administering is selected from the group of intramuscular administration, intravenous administration, subcutaneous administration, intradermal administration, and intraperitoneal administration.

21. (Currently amended) The method of Claim 1, 2, or 3, wherein said step of administering effects about 75% seroconversion in a population of felids administered said purified nucleic acid molecule.

22. (Currently amended) The method of Claim 1, 2, or 3, wherein said step of administering effects about 100% seroconversion in a population of felids administered said purified nucleic acid molecule.

23. (Currently amended) The method of Claim 1, 2, or 3, wherein said purified nucleic acid molecule:lipid ratio is from about 1:10 to about 10:1.

24. (Currently amended) The method of Claim 1, 2, or 3, wherein said purified nucleic acid molecule is administered in a dose of from about 75 micrograms to about 1,000 micrograms.

25. (Currently amended) The method of Claim 1, 2 or 3, wherein said purified nucleic acid molecule is administered in a dose of not more than about 75 micrograms.

26. (Original) The method of Claim 1, 2, or 3, wherein said composition is dehydrated and subsequently rehydrated prior to administration.

27. (Original) The method of Claim 1, 2, or 3, wherein said composition further comprises an excipient.

Remarks

Claims 1-5 and 21-25 have been amended to specify that the nucleic acid molecule be a 'purified nucleic acid molecule'. Support for purified nucleic acid molecules can be found, for example, on page 2, line 5 through line 6, of the specification. Additional support for purified nucleic acid molecules can be found, for example, on page 18, lines 1-5, of the specification which describe the use of a commercial kit in the preparation of an endotoxin-free nucleic acid molecule solution.

Claim 16 has been amended to remove the duplication of the words 'bobcat' and 'lynx'.

Rejections Under 35 U.S.C. § 103

The Examiner has rejected the instant Application under 35 U.S.C. §103 stating one of skill in the art would have been motivated to combine the teachings of Paoletti and McCluskie to produce the instant invention. Paoletti teaches the use of recombinant poxviruses to induce an immune response in a cat. McCluskie teaches complexing DNA with a cationic lipid.

As stated in the MPEP at 2142, one criteria necessary for establishing a *prima facia* case of obviousness, is that the prior art reference(s) must teach or suggest all the claim limitations. Applicants note that what they are claiming as their invention is a method of eliciting an immune response in cats using the process of DNA vaccination. The key point regarding DNA vaccination is that the DNA is purified away from any organism (e.g. bacteria, viruses) used to generate the necessary construct, prior to its administration into the animal. What is finally administered to the animal is relatively, pure DNA, free of intact organisms and substantially free of contaminating cell debris. Applicants point out that the instant claims have been amended to specify the composition administered to the felid comprise a purified nucleic acid molecule complexed with a cationic lipid. Applicants further note that what Paoletti teaches is a method of eliciting an immune response by administering a recombinant virus, not a purified DNA molecule. Since what Paoletti teaches is the use of recombinant virus, and what the instant claims are drawn to is the use of purified DNA, Applicants contend that Paoletti does not teach any limitation found in the instant claims and, therefore, the use of Paoletti in rejecting the newly amended claims would be in error.

Conclusion

In view of the above arguments, Applicants request the obviousness rejection be withdrawn and solicit an allowance of the instant claims.

If there are any questions, the Examiner is encouraged to contact the undersigned at (970) 493-7272 ext. 4174.

Respectfully submitted,

Dated: April 15, 2003

By: Richard J. Stern

Richard J. Stern, Ph.D.
Registration No. 50,668
Heska Corporation
1613 Prospect Parkway
Fort Collins, Colorado 80525
Telephone: (970) 493-7272
Facsimile: (970) 491-9976

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) and 1.27(c)) - SMALL BUSINESS CONCERN

I hereby declare that I am an official empowered to act on behalf of Heska Corporation of 1613 Prospect Parkway, Fort Collins, Colorado 80525, a small business concern.

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled "CATIONIC LIPID-MEDIATED ENHANCEMENT OF NUCLEIC ACID IMMUNIZATION OF CATS," and identified as Attorney File No. DE-3-C2-PUS, described in the specification filed August 10, 2001, and assigned Serial No. 09/830,221.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(c) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).
*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME_____
ADDRESS_____
[ ] INDIVIDUAL [ ] SMALL BUSINESS CONCERN [ ] NONPROFIT ORGANIZATION

NAME_____
ADDRESS_____
[ ] INDIVIDUAL [ ] SMALL BUSINESS CONCERN [ ] NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Dated: April 15, 2003

By: _____

Robert B. Grieve
Chairman and Chief Executive Officer
Heska Corporation
1613 Prospect Parkway
Fort Collins, Colorado 80525

Heska Corporation
Intellectual Property Dept.
1613 Prospect Parkway
Fort Collins, CO 80525

DATE: April 15, 2003
APPLICANT: Joel R. Haynes; Ramani S. Wonderling; Dan T. Stinchcomb
SERIAL NO.: 09/830,221
ATTY. FILE NO.: DE-3-C2-PUS (HKZ-034CPUS)
TITLE: "CATIONIC LIPID-MEDIATED ENHANCEMENT OF NUCLEIC ACID IMMUNIZATION OF CATS"

RECEIPT IS HEREBY ACKNOWLEDGED OF: Request for Extension of Time (of one month, charged to Deposit Account); Amendment and Response; Verified Statement (Declaration) Claiming Small Entity Status - Small Business Concern; deposited with the U.S. Postal Service as First Class Mail this date.